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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,994	11/12/1999	JAMES J. FORT,	6487USO1	1116

23492 7590 05/19/2008

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
05/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents_Abbott_Park@abbott.com
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Office Action Summary	Application No.	Applicant(s)	
	09/438,994	FORT, ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of RCE, amendment and remarks dated8-17-07 acknowledged.

Clams 24-32 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-17-07 has been entered.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmieri et al (already of record) in view of US 5,545,628 ('628) and US 6042847.

The instant application is claiming a pharmaceutical composition comprising:

1. A solid amorphous dispersion of fenofibrate or a salt or ester there of
2. Hydroxypropylmethylcellulose (HPMC)
3. Polyethylene glycol (PEG) carrier and a method of preparing the composition and method of treating hyperlipidemia comprising administering the composition.

Palmieri et al. teaches dissolution studies of Fenofibrate solid dispersions using Fenofibrate and PEG 4000 in solvent ethanol. See page 188, where the article teaches

that Fenofibrate is water insoluble molecule and is very soluble in ethanol and the article teaches PEG 4000 as a carrier because of its ethanol solubility and physiologically compatibility. Instant claims I, 3 and 18 use ethanol as solvent. Palmieri teaches that the amounts of PEG and fenofibrate dictate the solubility of the drug (page 192, col. 2). Palmieri fails to teach the claimed capsules or tablet formulations and instead only teaches the solid dispersions for improved solubility of the drug. Palmieri also lacks the claimed HPMC and the method of preparing the composition.

As explained in the previous action, '628 teach that fenofibrate is stabilized by the presence of HPMC by preventing the formation of crystals. However, '628 do not teach amorphous fenofibrate or does not teach solid dispersions such as Palmieri and instead teaches liquid formulations.

'847 teaches a pharmaceutical composition comprising a constant and controlled release of an amorphous active ingredient stabilized with polymers for a single daily peroral application such as tablets and capsules. '847 teach that the compositions are specifically for those that exist in amorphous form, which exhibits poor solubility in crystal form (col. 1, L 18-30, col. 5, L 12-25). '847 suggest that the pharmaceutical dosage form is in a three phase form, where a first phase has amorphous drug, water soluble polyvinylpyrrolidone and HPMC as carriers to inhibit the crystallization of the amorphous form of the drug, second phase containing sustained release agents and third phase containing gastro-resistant enteric film (col. 1). While '847 teach any of the known active agents or drugs that exhibit different polymorphic forms and a poor solubility in crystal form, '847 specifically teach the process of preparation in col. 8 and

examples. It would have been obvious fro one of an ordinary skill in the art at the time of the instant invention that fenofibrate has the disadvantage of forming crystals ('628), which being a poorly soluble drug would have the problem of poor bioavailability (as suggested by '847). Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the stabilizers such as PVP ('847) and HPMC ('628 or '847) with an expectation not only stabilize any crystals of fenofibrate but also render the drug to a stable amorphous state such that the solubility and thus the bioavailability of fenofibrate is obtained at the desired level because '847 teaches that the stabilizers such as PVP and HPMC stabilizes the amorphous form and also modifies release.

Response to Arguments

Applicant's arguments with respect to claims 24-32 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner,
Art Unit 1611
May 10, 2008